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# From Inception to Ingestion: The Cost of Creating New Drugs

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The pharmaceutical industry cites studies that suggest it costs more than $800 million to move a new drug through the 10-to-12 year discovery, development and approval process. However, critics claim those estimates are artificially inflated and that the actual costs are much lower. For example, Ralph Nader's Public Citizen released a study last year claiming that the cost of creating a new drug is only about $110 million (in 2000 dollars). And that includes the cost of failures.

Is there a way to resolve this discrepancy? Yes, by looking at aggregate research and development spending and the number of drugs finally approved.

**The Drug Creation Process.** The pharmaceutical industry is a high-technology — "pharmatech" — industry that pours billions of dollars annually into new, innovative drugs. But new drugs face numerous hurdles as they move from inception to ingestion — and those hurdles drive up the costs.

Scientists must first identify a chemical compound they think will help a medical condition. They then apply for a patent, which can take a couple of years before being issued. Researchers then must find a deliverable form of the drug and, in most cases, test it in animals.

If animal tests appear promising, the drug will begin moving through the human testing process, a series of three or four clinical trials that may test the drug on thousands of patients at various medical centers throughout the country, and sometimes internationally.

These trials can take six to eight years and thousands of medical personnel. There are numerous opportunities for failure. Often it isn't until the end of the clinical trials that enough patients are involved to determine if a drug's active ingredient is effective and if the side effects are acceptable.

And the patent clock is running all the while, despite the fact that the drug isn't yet on the market.

If patients are not responding as researchers had predicted, scientists may be able to adjust the formula, but they sometimes have to scrap the project and start over again, losing both time and the money invested.

If the drug makes it through the clinical trials and demonstrates to researchers that it is more effective than placebo (an inactive substance), the manufacturer sends the thousands of pages documenting the research to the Food and Drug Administration (FDA) for approval — a process that can also take more than two years (though there are ways to expedite it).

According to a 2001 study by economist Joseph DiMasi of the Tufts Center for the Study of Drug Development at Tufts University, for every 5,000 drugs that appear promising enough to be tested in animals, only five make it to human clinical trials and only one will actually be approved.

*Case Study: A "Youth Pill."* *The Wall Street Journal* recently reported that Pfizer spent $71 million researching a "youth pill" intended to stimulate the pituitary gland in hopes of reversing "the physical decline that comes with aging." Early tests on animals seemed very positive, but human trials were not as successful. Pfizer eventually and reluctantly discontinued its research. However, those costs can only be recovered through other drugs that successfully make it through the approval process.

**How Much Does It Cost to Create a New Drug?** Determining how much it costs to produce a new drug isn't an easy task. Some new drugs are tested on thousands of patients. Others target diseases that afflict relatively few people. Some may go through multiple

variations in either animal or human tests before the scientists get the right formula.

Moreover, the cost of a drug that actually reaches the market must incorporate the cost of those that failed — just as the price of products for sale in retail stores must reflect the cost of damaged, lost and stolen goods.

In 1991, DiMasi et al. published a paper in the *Journal of Health Economics* estimating that it cost about $231 million (in 1987 dollars) to take a new drug from creation to approval, including the cost of other drug failures and the interest lost had the money been invested rather than used for experiments. A few years later, the Boston Consulting Group (BCG) extrapolated the DiMasi study and concluded that it cost about $500 million to get a new drug to market.

BCG recently updated that figure. The firm interviewed about 60 scientists and executives from nearly 50 companies and academic institutions and concluded that it takes about $880 million and 15 years to get a single drug to market. And according to BCG's report, 75 percent of that cost is drug failures.

The DiMasi study produced for the Tufts Center and released last year also weighed in with a new estimate: the average drug takes about 12 years to move through the approval process and costs $802 million per approved drug.

**Another Way to Estimate Costs.** Another way to estimate the cost of creating a new drug is to look at total research and development costs — a number that has been tracked for years— and divide that amount by the number of new drugs approved each year, thus yielding the average cost of a new, approved drug. For example, the research-based pharmaceutical companies spent about $26 billion on R&D in 2000, and 27 drugs were approved. Thus, it cost approximately $964 million per drug approved in 2000.

The Cost of Creating a New Drug

| Year | R&D (billions) | Approved per Year | Cost per Approved Drug (millions) |
|---|---|---|---|
| 1987 | $5.5 | 21 | $262.0 |
| 1988 | $6.5 | 20 | $326.9 |
| 1989 | $7.3 | 23 | $318.7 |
| 1990 | $8.4 | 23 | $366.1 |
| 1991 | $9.7 | 30 | $323.5 |
| 1992 | $11.5 | 26 | $441.1 |
| 1993 | $12.7 | 25 | $509.6 |
| 1994 | $13.4 | 22 | $611.3 |
| 1995 | $15.2 | 28 | $543.1 |
| 1996 | $16.9 | 53 | $319.0 |
| 1997 | $19.0 | 39 | $487.4 |
| 1998 | $21.1 | 30 | $702.0 |
| 1999 | $22.7 | 35 | $649.1 |
| 2000 | $26.0 | 27 | $964.1 |

**Source**: Pharmaceutical Research and Manufacturers of America

Of course, this approach is not as scientifically rigorous as the other methods. And cost estimates can vary significantly if a disproportionate share of new drugs appears in one year, as in 1996.

Nevertheless, tracking R&D spending and the number of approved drugs over a series of years will provide a relatively accurate estimate of the cost of producing new drugs along with identifying the cost trends.

This approach also highlights the shortfalls of the Public Citizen study. If drug companies only spent $110 million to get a new drug approved (in 2000), including the failed drugs, but spent a total of $26 billion on R&D, then some 236 news drugs should have been approved that year.

**Is Innovation Declining?** With only a few exceptions, the number of drugs approved each year has been fairly stable. Of course, some new drugs are intended to capture part of the market of an existing drug. That's just competition, and it has helped to hold prices down. For example, after the launch of a new generation of antidepressants (Prozac) in 1987, the next five antidepressants were introduced at 7 to 45 percent less than the original launch price.

But nothing, not even lower prices, seems to placate the critics. If there is only one patented drug for a specific medical condition, they decry the high price and lack of competition. If there are several drugs treating the same condition, they complain that money is being wasted on researching and marketing "me-too" drugs.

**Conclusion**. Everyone agrees that it takes millions of dollars to take a drug through the approval process. The question is how many millions? By dividing the R&D costs by the number of drugs approved in a given year, we can get a rough but accurate picture over time of the money it takes to move a drug from inception to ingestion.

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